

REMARKS

Reconsideration of the present application as amended is requested. Applicants have amended the application to cancel claim 36 and rewrite claim 37 in independent form by incorporating the limitations of claim 36. Applicants have also cancelled claims 48-51, leaving only now independent 37 and its dependent claim 38, and previously presented independent claim 41 and its dependent claims 42-47. No substantive amendments have been made to the claims.

The previously presented grounds for rejection based on the published application of Biedermann (U.S. 2005/0154390) have been repeated in this Final Office Action. Biedermann was said to anticipate claim 36, but since this claim has been cancelled without prejudice that rejection is moot. Biedermann was also cited as rendering claims 37, 38, 41-47 obvious when combined with additional references. In addition, the published application of Ferree (U.S. 2003/0220643) was said to anticipate claim 48 and render its dependent claims 49-51 obvious when combined with a patent to Bao. Since claims 48-51 have been cancelled without prejudice the rejections based on Ferree are believed to be moot.

With the present amendment, the only outstanding rejections from the Final Action are the obviousness rejections of: claims 37, 41, 46 and 47 (in view of the combination of Biedermann with Ferree); claims 38 and 42-44 (Biedermann, Ferree and Bao et al., U.S. No. 5,534,028); and claim 45 (Biedermann, Ferree, Bao and Fleischmann et al., U.S. No. 6,375,682). The Biedermann reference is central to each of the rejections.

In a prior response, Applicants submitted the Declaration Under 37 C.F.R. 1.131 of Lawrence Boyd [the Boyd §131 Declaration], swearing behind the Biedermann reference. The Declaration established that the present claimed invention as defined in claim 41 was conceived prior to the earliest listed filing date for the Biedermann publication of November 7, 2003. The declaration also sought to establish that Mr. Boyd, the other named inventors and outside counsel worked diligently during the period from November 7, 2003, to December 31, 2003, to constructively reduce the invention to practice in the form of the present application filed less than two months after the Biedermann application was filed.

In the Final Office Action, the Boyd §131 Declaration was dismissed as ineffective to overcome the Biedermann reference. The first defect was noted with respect to Applicants'

claim 36. Since this claim has been cancelled without prejudice this alleged deficiency is moot.

The Boyd §131 Declaration was said to be ineffective with respect to claim 41 because it did not establish conception of the claimed subject matter prior to the Biedermann November 7, 2003, filing date. Specifically it was asserted that the Declaration did not mention introducing a device into an intervertebral space in combination with a dynamic stabilization system. This assertion is incorrect. Exhibit A to the Boyd §131 Declaration discusses the use of intradiscal arthroplasty in Section 3, para. 3, including mention of "articulating discs and polymeric nucleus pulposus replacements", both of which are devices introduced into an intervertebral space. This same paragraph explains that the availability of these intradiscal devices has generated "broad interest in means of providing for enhanced spinal stabilization, while allowing some degree of mobility." The statement of the "purpose and/or novel features of the invention" in Section 4 of Exhibit A, spinal fusion is discussed and explains that with the present invention, "Surgeons will utilize elements commonly used for fusion, with the ability to incorporate flexibility within the screw and screw/rod or screw/plate connections."

Attachment E to the Invention Disclosure Form of Exhibit A to the Boyd §131 Declaration includes a statement "DUCK BILL IN ANNULOTOMY TO PREVENT IDN IN ANNULOTOMY – SELF SEAL". The term "IDN" in this statement is an abbreviation for "Injectable Disc Nucleus", a term which is used by the assignee of the subject invention to describe a biomaterial that is injected into the intradiscal space and that is intended to simulate the properties of the natural disc in order to restore as much as possible of the natural motion of the disc. This statement clearly discloses the use of a device within an intervertebral space used in connection with the dynamic stabilization system of the present invention. This statement is in a document that is dated prior to the November 7, 2003, the earliest filing date of Biedermann, as asserted in the Boyd §131 Declaration, and thus establishes conception of the invention of claim 41 prior to that critical date.

Further support for this early conception is supplied by the Declaration Under 37 C.F.R. §1.131 of Robert M. Rodrick [the Rodrick §131 Declaration], which accompanies this response. As stated in Paragraph 3 of this new declaration, Mr. Rodrick was in attendance at

the meeting at which the above-noted statement was written. Mr. Rodrick testifies that the meeting and the particular statement occurred prior to November 7, 2003. In Paragraph 4, Mr. Rodrick also explains that at a subsequent meeting, but still prior to November 7, 2003, the use of the dynamic stabilization system of the present application in conjunction with an IDN was again discussed, as reflected in Mr. Rodrick's notes attached as Exhibit A to the declaration. These notes included the statement, "Can use in conjunction with IDN as a means of partially stabilizing the spinal segments, without making it totally rigid." Again, the term "IDN" means "Injectable Disc Nucleus", as explained above. This evidence, attested to by Mr. Rodrick, unequivocally establishes conception of the invention of claim 41 prior to the November 7, 2003 filing date of the Biedermann application.

The previously submitted Boyd §131 Declaration and its attachments establish conception of the invention of claim 41 prior to the Biedermann filing date. Thus, the Boyd §131 Declaration alone is sufficient to traverse the deficiency alleged in the Office Action regarding claim 41. Moreover, the Rodrick §131 Declaration also establishes prior conception of the claimed invention. At a minimum, the Rodrick §131 Declaration corroborates the disclosure of this earlier conception in the attachments to the Boyd §131 Declaration. It is therefore believed that this ground for refusing consideration of the Boyd §131 Declaration has been traversed.

Finally, it was alleged that the evidence in the Boyd §131 Declaration was insufficient to establish diligence during the critical period because actual dates were not identified. The Rules of Patent Practice state that a declaration under §131 must show facts that are "such, in character and weight, to establish ... conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent ... filing of the application." 37 C.F.R. §1.131. The requirement for actual dates to prove diligence is not set out in the Rules, however, M.P.E.P. 715.07(II) states that actual dates of acts used to establish diligence must be set forth (in contrast to the date-redaction practice accepted for proving conception). While the Boyd §131 Declaration lacked actual dates of the diligence acts, Applicants have provided such dates in the Rodrick §131 Declaration accompanying this response. As indicated in the declaration, Mr. Rodrick is Chief Patent Counsel for the assignee of this application and deals directly with company inventions from conception to

constructive reduction to practice in a patent application. As explained in the Rodrick §131 Declaration, a first draft of the patent application was provided by outside counsel prior to the Biedermann filing date. The majority of the subsequent acts were directed toward completing the constructive reduction to practice in the form of the final application filed on December 31, 2003. Mr. Rodrick outlines in detail and with specific dates the acts undertaken by himself, the inventors and the outside counsel who prepared the patent application. Three drafts of the patent application were exchanged, reviewed and revised during the period from November 7 to December 31. See, Paras. 5, 10 and 13. Final corrections were discussed two days prior to filing. See, Para. 15.

In addition to the acts directed to the preparation of the patent application, the parties were exchanging potential prior art for evaluation in light of the invention. See, Paras. 9 and 11. One of the inventors was also taking steps toward an actual reduction to practice by initiating a study of the fatigue resistance and mechanical strength of the various embodiments. See, Paras. 6 and 8. Mr. Rodrick further notes that the Thanksgiving and Christmas Holidays fell during this period which made communication among the parties more difficult. See, Paras. 10, 11 and 13.

In sum, in his §131 Declaration Mr. Rodrick attests to specific acts and actual dates of these acts all falling within the critical period between November 7, 2003 and December 31, 2003. These facts conclusively establish reasonable diligence by the inventors, in-house counsel and outside counsel from a date prior to the Biedermann filing date to the constructive reduction to practice in the form of the present application. Applicants have therefore traversed the final ground for refusing consideration of the Boyd §131 Declaration. The §131 Declarations of Mr. Boyd and Mr. Rodrick establish prior conception, coupled with diligence to a constructive reduction to practice, that predates the Biedermann published application. Applicants have thus sworn behind Biedermann and removed it as a reference against the pending claims. Absent Biedermann, all of the obviousness rejections must fall.

It is requested that the rejections of pending claims 37-38 and 41-47 be withdrawn and that action be taken toward a Notice of Allowance.

Respectfully Submitted,

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